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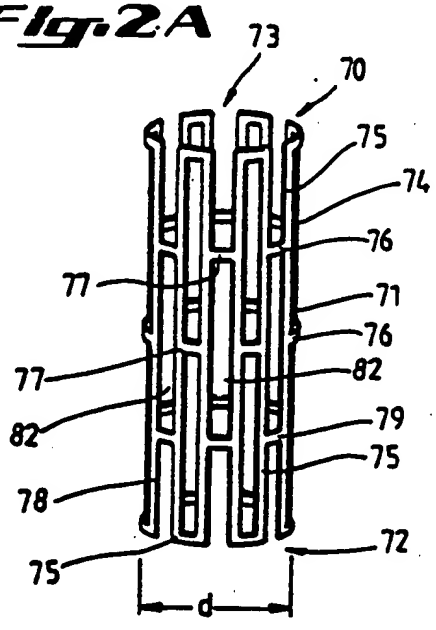
(54) Expandable intraluminal graft, and apparatus for implanting an expandable intraluminal graft.

(57) An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a wire mesh tube or a thin-walled tubular member having a plurality of openings formed therein.

Fig.2A



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dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observe in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing of the body passageway by the expanded graft.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expand able intraluminal vascular graft. The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the walls surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular shaped member; the tubular shaped member having a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen; and the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway.

A further feature of the present invention is that the plurality of elongate members may be a plurality of wires, and the wires may be fixedly secured to one another where the wires intersect with one another. An additional feature of the present invention is that the plurality of elongate members may be a plurality of thin bars which are fixedly secured to one another where the bars intersect with one another. A further feature of the present invention is that the tubular shaped member may have a biological intert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for expanding the lumen of a body passageway. The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen.

A further feature of the present invention is that the portion of the catheter in contact with the intraluminal graft may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter

rowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use and the term "prosthesis" emcompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" emcompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIG. 1A, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular shaped member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Preferably, the wall surface 74 is formed by a plurality of intersecting elongate members 75, 76 with at least some of the elongate members 75, 76 intersecting with one another intermediate the first and second ends 72, 73 of the tubular shaped member 71, such as shown at intersection points 77. Tubular shaped member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular shaped member 71 into a body passageway 80 having a lumen 81. With reference to FIG. 1B, upon the application from the interior of the tubular shaped member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular shaped member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and dependent upon the amount of force applied to the tubular shaped member 71.

With reference to FIGS. 1A and 1B, elongate members 75, 76, which form wall surface 74 of tubular shaped member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Elongate members 75, 76 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular shaped membr 71 to be expanded from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular shaped member 71 to retain its expanded configuration with the enlarged diameter d' shown in FIG. 1B. Suitable materials for the fabrication of tubular shaped member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described. Preferably, elongate members 75, 76 are fabricated from stainless steel. Preferably, the elongate members 75, 76 illustrated in FIGS. 1A and 1B are small diameter stainless steel wires having a cylindrical cross-section. It should of course be understood that each elongate member 75, 76, could have other cross-sectional configurations, such as triangular, square, rectangular, hexagonal, etc. Further, it is preferable that the plurality of elongate members 75, 76 are fixedly secured to one another where the elongate members 75, 76 intersect with one another, such as at the intersection points 77. Elongate members 75, 76 could be fixedly secured to one another in any conventional manner, such as by welding, soldering, or gluing, such as with a suitable epoxy glue; however, it is preferred that the intersection points 77 are soldered with silver. By fixedly securing the elongate members 75, 76, to one another, tubular member 71 is provided with a relatively high resistance to radial collapse, and the tubular shaped member 71 has the ability to retain its enlarged diameter, d', as shown in FIG. 1B. Preferably, tubular shaped member 71 is made of continuous, stainless steel wire woven in a criss-crossed tubular pattern to form what can be generally described as a wire mesh tube.

When fabricating tubular shaped member, or wire mesh tube, 71, it can be initially fabricated in the configuration shown in FIG. 1A with diameter, d. Alternatively, it can be fabricated with a diameter which is larger than initial diameter d and after fabrication, tubular shaped member 71 could be carefully collapsed to have diameter d shown in FIG. 1A. During the collapsing of tubular shaped member, or wire mesh tube, 71, care must be taken to insure that overlapping of adjacent elongate member 75, 76 is avoided. It should of course be understood that upon expansion of tubular shaped member, or wire mesh tube, 71 into the configuration shown in FIG. 1B, the distance between first and second ends 72 and 73 will of course decrease.

With reference now to FIGS. 2A and 2B, another embodiment of expandable intraluminal vascular graft, or prosthesis, 70, is illustrated. The same reference numerals are utilized and are applicable for elements previously described in FIGS. 1A and 1B. The intraluminal vascular graft, or prosthesis, 70 of FIGS. 2A and 2B differs from that previously described in connection with FIGS. 1A and 1B, in that the plurality of elongate members 75 and 76 are a plurality of thin bars 78, 79 which are preferably fixedly secured to one another where the bars 78, 79 intersect with one another. Bars 78, 79 preferably have a thin, rectangular cross-sectional configuration, and may be joined to one another in any conventional manner, such as by welding, brazing, soldering, or may be formed integral with one another. Preferably, tubular shaped member 71 is initially a thin-walled stain-

80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of the left main artery, it is believed that the intimal flap will be unable to enter the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through openings 82 of graft 70. If is further believed that intact patches of endothelium between the elongate members 75, 76, 78, 79 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obviously modifications and equivalents will be apparent to one skilled in the art. For example, the means for expanding the prosthesis or graft could be a plurality of hydraulically actuated rigid members disposed on a catheter, or a plurality of angioplasty balloons could be utilized to expand the prosthesis or graft. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

Claims

1. An expandable intraluminal vascular graft, comprising:
a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular shaped members;
the intersecting elongate members being a plurality of thin bars, each bar having a uniform thin rectangular cross-sectional configuration;
the tubular shaped member having a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen; and
the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway.

2. The expandable intraluminal vascular graft of claim 1 , wherein the plurality of thin bars are fixedly secured to one another where the bars intersect with one another.

3. An expandable prosthesis for a body passageway, comprising:
a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular shaped member;
the intersecting elongate members being a plurality of thin bars, each bar having a uniform, thin rectangular cross-sectional configuration;
the tubular shaped member having a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen; and
the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway.

4. The expandable prosthesis for a body passageway of claim 3 , wherein the plurality of thin bars are fixedly secured to one another where the bars intersect with one another.

5. An apparatus for intraluminally reinforcing a body passageway, comprising:
an expandable, tubular shaped prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, the intersecting elongate members being a plurality of thin bars, each bar having a uniform, thin rectangular cross-sectional configuration; and
a catheter, having an expandable, inflatable portion

Fig. 1A

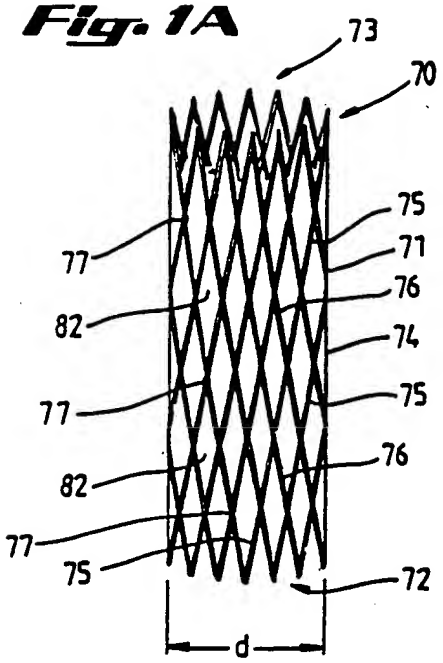

Fig. 1B

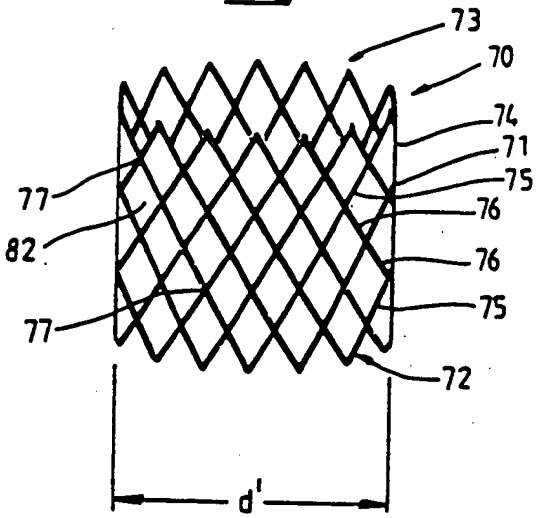

Fig. 2A

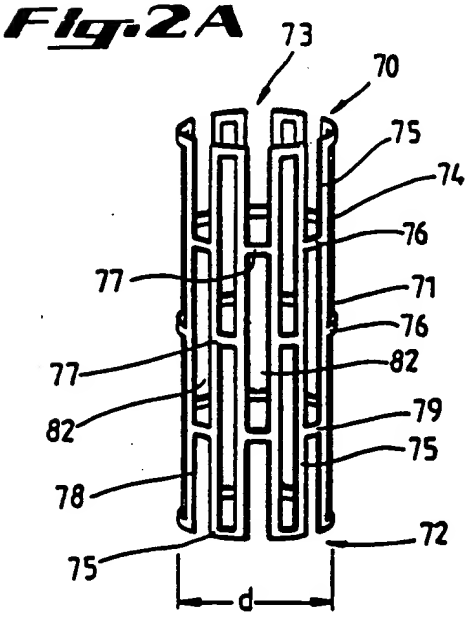

Fig. 2B